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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/899,495 | 07/05/2001 | Christopher W. Benjamin | 00180.US1/PHRM-0340 | 2579 |

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/899,495

Applicant(s)

BENJAMIN ET AL.

Examiner

Robert Landsman

Art Unit

1647

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-148 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-148 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

1. Election/Restriction

A. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-22, 25-29, 75-96 and 99-103, drawn to a polynucleotide, vectors, host cell cells and methods of producing a polypeptide and compositions, classified in class 435, subclass 69.1.
- II. Claims 23, 24, 97 and 98, drawn to antisense polynucleotides, classified in class 514, subclass 44.
- III. Claims 30-35 and 104-109, drawn to a polypeptide and a composition, classified in class 530, subclass 350.
- IV. Claims 36-38, 110 and 111, drawn to an antibody and a composition, classified in class 530, subclass 387.1.
- V. Claims 39 and 113, drawn to a method of inducing an immune response by administering a polypeptide, classified in class 514, subclass 2.
- VI. Claims 40-43, 48-51, 114-117 and 122-125, drawn to a method of identifying a compound which binds and/or modulates ion-x, classified in class 435, subclass 7.1.
- VII. Claims 44, 52, 118 and 126, drawn to a compound which binds and/or modulates ion-x, class and subclass undeterminable.
- VIII. Claims 45, 46, 119 and 120, drawn to a method of identifying a compound which binds a nucleic acid encoding ion-x, classified in class 435, subclass 6.
- IX. Claims 47 and 121, drawn to a compound which binds a nucleic acid encoding ion-x, class and subclass undeterminable.
- X. Claims 53-55 and 127-129, drawn to a method of identifying an animal homolog of ion-x by comparing nucleic acid sequences, classified in class 435, subclass 6.
- XI. Claims 56-63 and 130-137, drawn to a method of identifying mutations in a polynucleotide, and a kit, classified in class 435, subclass 6.
- XII. Claims 64-68 and 138-142, drawn to an isolated polynucleotide variant and a host cell, classified in class 435, subclass 69.1.
- XIII. Claims 69 and 143, drawn to a method of identifying a modulator of a biological activity of a mutant polypeptide, classified in class 435, subclass 7.2.

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- XIV. Claims 70, 72-73 in part, 144 and 146-147 in part, drawn to a method of identifying compounds useful in treating a disorder, classified in class 435, subclass 7.1.
- XV. Claim 71, 72-73 in part, 145 and 146-147 in part, drawn to a method of identifying compounds useful as a modulator between ion-x and a binding partner, classified in class 435, subclass 7.1.
- XVI. Claims 74 and 148, drawn to a chimeric receptor, classified in class 530, subclass 402.

B. The inventions are distinct, each from each other because of the following reasons:

Inventions I, II, III, IV, VII, IX, XII and XVI are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. The polynucleotide of Invention I can be used to make a hybridization probe, or can be used in gene therapy as well as to produce the protein of interest. The polynucleotide of Invention II is used in gene therapy. The protein of Invention III can be used for purposes other than to make an antibody of Invention IV, such as a probe, or used therapeutically or diagnostically (e.g. in screening). The antibody of Invention IV can be used for reasons other than to obtain the protein of Invention III. For example, the antibody may be used in diagnostics (e.g. as a probe in immunoassays, or in immunochromatography), or therapeutically. The compounds of Invention VII and IX can be used diagnostically (e.g. either in receptor binding or receptor function assays), or therapeutically.

Inventions I and VIII, X, XI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process of using that product MPEP § 806.05(h).

Inventions I, II are unrelated to V, VI and XIII-XV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Invention II is unrelated to Inventions VIII, X, XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Invention III and V, VI, XIV, XV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process of using that product MPEP § 806.05(h).

Invention III is unrelated to Inventions VIII, X, XI, XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Invention IV is unrelated to Inventions V, VI, VIII, X, XI, XIII-XV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions V, VI, VIII, X, XI, XIII-XV are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Invention V and VI are unrelated to Inventions VII, IX, XII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Invention VII and IX are unrelated to Inventions VIII, X, XI, XIII-XV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Invention VIII is unrelated to Inventions IX, XII, XVI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Invention X and XI are unrelated to Inventions XII, XVI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

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Invention XII is unrelated to Inventions XIII-XV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Invention XVI is unrelated to Inventions XIII-XV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Furthermore, these claims are drawn to at least SEQ ID NO:1-118. Therefore, in addition to electing a Group, Applicants are required to elect one SEQ ID NO to be searched and its corresponding polynucleotide or polypeptide sequence.

C. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17 (h).

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Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
April 22, 2003


ROBERT LANDSMAN
PATENT EXAMINER